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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,296	03/13/2001	Vladimir Efimov	AM-00102.P.1-US	2109

7590 07/20/2005

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EXAMINER	
MCKENZIE, THOMAS C	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/805,296	EFIMOV ET AL.	
	Examiner	Art Unit	
	Thomas McKenzie, Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2005* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *108-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *108,109,112 and 113* is/are allowed.

6)☒ Claim(s) *110 and 111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5,10,16*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

TCM

S.O.O.

DETAILED ACTION

1. This action is in response to amendments filed on 4/28/05. Applicant has not amended any claims. Claims 110 and 111 were previously rejected. Claim 108, 109, 112, and 113 were previously allowed.

Abstract

2. Applicant is still reminded of the proper content of an abstract of the disclosure. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." The abstract is too generic. Examiner suggests claim 108, including the figure.

Applicants remark they wish this objection held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 110 and 111 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a phosphono peptide

nucleic acid monomer" is indefinite. Again, nowhere in the specification is this term defined *verbatim*. What is the structure of this radical? In lines 24-27, page 2 Applicants introduce the abbreviation "pPNAs" for phosphono peptide nucleic acid. In lines 16-19, pages 12, Applicants define "a phosphono peptide nucleic acid" but fail to specify if this is a monomer. They use the open language terms "comprising" and "such as". What other structures are included in the term? In lines 23-26, page 13, Applicants define "monomer unit of a peptide nucleic acid" but fail to specify if this is a phosphorus containing peptide. The definition includes "nucleobase (or nucleobase analogue, nucleobase-binding unit, ligand, intercalator, reporter group or label)". The indefiniteness of these terms has been discussed in the previous office action. The nucleobase "is covalently attached to an amino acid or amino acid derivative or analog". Does amino acid refer to the twenty naturally occurring amino acids, which are coded for in DNA, or are all compounds containing any acid and amine group intended? The issue of derivative or analogue was discussed previously. The three structures **II-IV**, pages 20, 22, and 24 are described as hydroxyproline and aryl phosphono peptide nucleic acid monomers. Is this what is meant or are other radicals also to be included? The Examiner understands that hydroxyproline is an amino acid, which may be incorporated into a peptide, but hydroxyproline itself is not a peptide. An aryl

group is not a peptide but structure IV apparently may contain additional peptides in radicals G and E. The Examiner suggests using structures **II-IV**, if that is what is intended.

Page 37 of the specification defines "a hydroxyproline peptide nucleic acid phosphono peptide nucleic acid dimer" or "HypNA-pPNA" dimer". This does not define *ipso verba* the meaning of "a phosphono peptide nucleic acid monomer". A monomer and a dimer are not the same thing. Removal of a hydroxyl proline from Formula (VIII) leaves N(T) $C(R^{12})(R^{13})$ $C(R^{14})(R^{15})$ $N(A^2\text{-}B^2)$ $C(R^{16})(R^{17})$ $P(O)(O^-)$E. There is no way to divide this dimer radical in half to determine which is the monomer under discussion.

Page 40 discloses "a phosphono peptide nucleic acid-hydroxyproline peptide nucleic acid dimer" or "pPNA-HypNA" dimer". Page 42 discloses "a serine peptide nucleic acid-phosphono peptide nucleic acid dimer" or "SerNA-pPNA" dimer". Page 44 discloses "a phosphono peptide nucleic acid-serine peptide nucleic acid dimer" or "pPNA-SerNA" dimer". These three dimer formulas certainly contain the phrase " phosphono peptide nucleic acid" but do not *ipso verba* define what is meant by "a phosphono peptide nucleic acid monomer". The structures themselves are internally inconsistent.

Removal of a hydroxyl proline from Formula (IX) leaves G-N(T) $C(R^{12})(R^{13})$ $C(R^{14})(R^{15})$ $N(A^2\text{-}B^2)$ $C(R^{16})(R^{17})$ $P(Q)(O^-)E$. This differs by the presence of variable G and Q from the dimer discussed above. Again, there is no way to divide this dimer radical in half to determine which is the monomer under discussion.

When the Examiner mentally removes what appears to be a serine peptide nucleic acid residue from "a serine peptide nucleic acid-phosphono peptide nucleic acid dimer" (X) what remains is N(T) $C(R^{12})(R^{13})$ $C(R^{14})(R^{15})$ $N(A^2\text{-}B^2)$ $C(R^{16})(R^{17})$ $P(O)(O^-)E$.. While this is the same residue found on page 37 it differs from the residue found on page 40 and differs from the residue found on page 42.

When the Examiner mentally removes what appears to be serine peptide nucleic acid residue from "a phosphono peptide nucleic acid-serine peptide nucleic acid dimer" (XI) what remains is G-N(T) $C(R^{12})(R^{13})$ $C(R^{14})(R^{15})$ $N(A^2\text{-}B^2)$ $C(R^{16})(R^{17})$ $P(Q)(O^-)E$. This is the same residue as found on page 40 but differs from those shown on pages 37 and 42. Which residue represents the structure of "a phosphono peptide nucleic acid monomer"? Are all structures being claimed? Are there others? How does one determine the monomer structure being claimed from the dimer structures shown in the specification?

Applicants make two arguments concerning this rejection. They agree that there are errors in the structures presented in the previous remarks and argue that to make "a phosphono peptide nucleic acid monomer" one must mentally remove "serine peptide nucleic acid" from the "a phosphono peptide nucleic acid-serine peptide nucleic acid dimer" pictured in structures X and XI on pages 42 and 44. This is not persuasive. Firstly, not only do the remarks contain inconsistencies and errors but as demonstrated above the specification itself is completely inconsistent. Concerning the second argument, attempting to form "a phosphono peptide nucleic acid" from structure XI by the usual processes of chemical structure building one is left with a diradical containing both a G and a Q radical. Performing the same operation from structure X, one is left with a diradical containing a new oxygen atom but not containing G or Q. Which one is the structure of "a phosphono peptide nucleic acid monomer"?

The Examiner in the previous action raised a number of questions regarding the structure under discussion. If applicants cannot answer the questions how then is the public to determine intended scope? As stated in *In re Zletz*, 13 USPQ2d 1320, 1322, "[a]n essential purpose of patent examination is to fashion claims that are precise, clear, correct and unambiguous." The U.S. Court of Customs and Patent Appeals held in *In re Prater and Wei* 162 USPQ 541, "this court has

consistently taken the tack that claims yet unpatented are to be given the broadest reasonable interpretation consistent with the specification during the examination of a patent application since the applicant may then amend his claims, the thought being to reduce the possibility that, after the patent is granted, the claims may be interpreted as giving broader coverage than is justified." This term is ambiguous.

In a previous telephone interview, Applicants proposed incorporating the formulas of their desired phosphono peptide radical into the structures but have failed do do so.

Allowable Subject Matter

4. Claims 108, 109, 112, and 113 remain allowed. Claims 110 and 111 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

7. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (571) 273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.

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